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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Casey,Lindsay J.
F.R. KELLY & CO.
27 Clyde Road
Ballsbridge
Dublin 4
IRLANDE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	13.11.2000
Applicant's or agent's file reference	**IMPORTANT NOTIFICATION**
pf04403/ljc	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB00/00205	08/02/2000	08/02/1999

Applicant
ALLEN, James et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith th international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/
European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer
Edel, M
Tel.+49 89 2399-2426

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
pf04403/ljc		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB00/00205	08/02/2000	08/02/1999
International Patent Classification (IPC) or national classification and IPC A61N1/39		
Applicant ALLEN, James et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24/08/2000	13.11.2000
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Wetzig, T Telephone No. +49 89 2399 7412

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB00/00205

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1-21 as originally filed

Claims, No.:

1-7 as originally filed

Drawings, sheets:

1/15-15/15 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in th language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (und r Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-7
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-7
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-7
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

1. In this report reference is made to the following document:

   D1....EP-A-0 674 917

ad V:

1.1. Document D1, which is considered to represent the most relevant prior art, discloses a device for determining when a patient is susceptible to defibrillation. The device disclosed in document D1 comprises data processing means for determining the instant of defibrillation by checking if the ECG signal (and signals derived from ECG) are reaching/crossing certain thresholds.

Claim 1 differs in the following:

the data processing means are adapted to determine a region of the ECG signal where such signal passes from a first threshold to a second threshold at least equal in magnitude to that of the first threshold and of opposite polarity thereto while the gradient of such signal remains within certain limits.

None of the documents cited in the international search report discloses a device comprising data processing means adapted to determine the instant of defibrillation by checking if the ECG signal is passing from a first threshold to a second threshold having a polarity opposite to the polarity of the first threshold.

Therefore, the subject-matter of claim 1 is considered as novel (Article 33(2) PCT).

1.2. The subject-matter of claim 1 is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

Claim 1 defines an alternative device for determining when a patient is susceptible to defibrillation.

1.3. Claims 2-7 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

ad VII:

1. Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).

2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

3. To meet the requirements of Rule 5.1(a)(ii) PCT, the document D1 should have been identified in the description and the relevant background art disclosed therein should have been briefly discussed.

4. The figure number "10" on page 15, line 33, and on page 16, line 4 appears incorrect, since figure 10 does not show dashed lines.

5. On page 17, line 23, the term "as indicated by the dashed line" appears incorrect, since figure 12 does not show a dashed line.

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

CASEY, Lindsay, Joseph
F.R. Kelly & Co.
27 Clyde Road
Ballsbridge
Dublin 4
IRLANDE

Date of mailing (day/month/year)
19 March 2001 (19.03.01)

Applicant's or agent's file reference
pf04403/ljc

IMPORTANT NOTIFICATION

International application No.
PCT/IB00/00205

International filing date (day/month/year)
08 February 2000 (08.02.00)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address

State of Nationality: GB
State of Residence: GB
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [ ] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address

HEARTSINE TECHNOLOGIES, INC.
Valley Business Centre
67 church Road
Newtownabbey
County Antrim BT36 7LS
United Kingdom

State of Nationality: GB
State of Residence: GB
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:
Assignment to the above-named applicant.

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

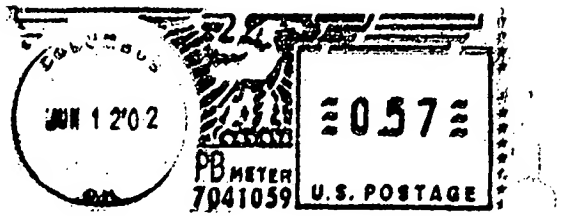
Facsimile No.: (41-22) 740.14.35

Authorized officer
R. Raissi

Telephone No.: (41-22) 338.83.38

PORTER WRIGHT
MORRIS & ARTHUR
Attorneys & Counselors at Law

41 South High Street
Columbus, Ohio 43215-6194



The Honorable Commissioner for Patents
Box Missing Parts
Washington, D.C. 20231

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 03 October 2000 (03.10.00)	
International application No. PCT/IB00/00205	**Applicant's or agent's file reference** pf04403/ljc
International filing date (day/month/year) 08 February 2000 (08.02.00)	**Priority date** (day/month/year) 08 February 1999 (08.02.99)
Applicant ALLEN, James et al	

1. The designated Office is hereby notified of its election made:

   [X] in the demand filed with the International Preliminary Examining Authority on:

   24 August 2000 (24.08.00)

   [ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

   [ ] was not

   made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Juan Cruz

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TRE

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

To:
F.R. KELLY & CO.
Attn. Casey,Lindsay J.
27 Clyde Road
Ballsbridge
Dublin 4
IRELAND

Applicant's or agent's file reference pf04403/1jc	Date of mailing *(day/month/year)* 07/06/2000 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/IB 00/ 00205	International filing date *(day/month/year)* 08/02/2000
Applicant ALLEN, James et al.	

1. [X] The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Irene Rbia-Brand

Form PCT/ISA/220 (July 1998)

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international pbulication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (co ued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped),whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
pf04403/1jc		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/IB 00/00205	08/02/2000	08/02/1999
Applicant		
ALLEN, James et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 11

   [ ] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [X] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 00/00205

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/39 A61B5/0456

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N A61B G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 545 182 A (STOTTS LAWRENCE J ET AL) 13 August 1996 (1996-08-13) column 4, line 61 -column 5, line 29 column 9, line 15-32	1
A	EP 0 674 917 A (VENTRITEX INC) 4 October 1995 (1995-10-04) column 6, line 23-55	1
A	US 5 578 062 A (ALT ECKHARD ET AL) 26 November 1996 (1996-11-26) column 5, line 29-43 column 7, line 17-35 column 8, line 22-30	1
A	US 5 507 778 A (FREEMAN GARY A) 16 April 1996 (1996-04-16) column 5, line 13-27	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 May 2000	07/06/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Grossmann, C.

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB 00/00205

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5545182	A	13-08-1996	EP	0729371 A	04-09-1996
			JP	9505762 T	10-06-1997
			WO	9609088 A	28-03-1996
EP 0674917	A	04-10-1995	US	5500008 A	19-03-1996
			CA	2142163 A	30-09-1995
			US	5531767 A	02-07-1996
			US	5749901 A	12-05-1998
US 5578062	A	26-11-1996	CA	2192847 A	24-10-1996
			EP	0772476 A	14-05-1997
			JP	10503962 T	14-04-1998
			WO	9632984 A	24-10-1996
US 5507778	A	16-04-1996	WO	9522372 A	24-08-1995

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61N 1/39, A61B 5/0456

A1

(11) International Publication Number: WO 00/47279

(43) International Publication Date: 17 August 2000 (17.08.00)

(21) International Application Number: PCT/IB00/00205

(22) International Filing Date: 8 February 2000 (08.02.00)

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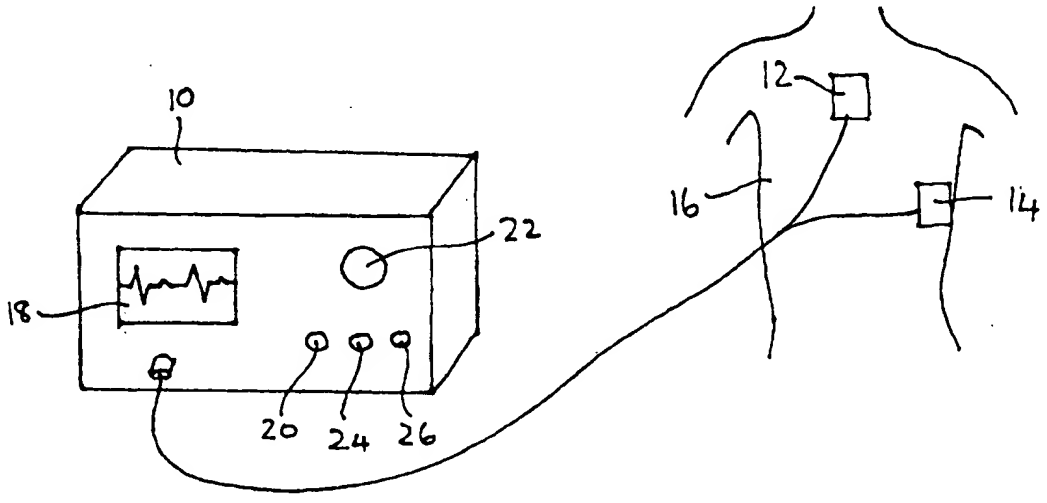

(57) Abstract

An apparatus for determining when a patient is susceptible to defibrillation comprises a plurality of electrodes (12, 14) for obtaining an ECG signal from a patient, and data processing means (30, 42) for determining a region of the ECG signal where the signal passes from a first threshold to a second threshold at least equal in magnitude but of opposite polarity to the first threshold while the gradient of the signal remains within certain limits, detecting the next following ECG signal peak, and providing an output signal upon such detection.

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APPARATUS FOR DETERMINING WHEN A PATIENT IS SUSCEPTIBLE TO DEFIBRILLATION

This invention relates to an apparatus for determining when a patient is susceptible to defibrillation.

Ventricular fibrillation (VF) is an abnormal rhythm of the heart which proves fatal if left untreated. The only effective treatment in an emergency situation is a high voltage shock applied to the heart either through electrodes applied to the chest wall or through electrodes attached directly onto the heart's surface. This high voltage shock attempts to interrupt the Ventricular fibrillation sequence and thereby restore the heart to a normal activation sequence.

A heart in VF is not effective and circulates very little blood, if any at all. A VF event is therefore probably the most time critical of all medical cases. With no blood circulation, brain tissue death or necrosis is imminent within minutes of the event occurring. The lack of blood supply to the body also compounds the time critical nature of the event because the heart itself requires blood supply via its coronary arteries in order to function efficiently. During VF with the blood supply to the whole body interrupted, the heart begins to experience ischaemia. Ischaemic heart tissue is more prone to VF than normal heart tissue. This means that as the VF rhythm persists, the ability to correct the sequence reduces and the risk of death increases.

There are various different mechanisms by which the

Ventricular fibrillation sequence can maintain itself. Unlike Normal Sinus rhythm (a one shot sequence being actively initiated by the Sino-atrial Node), VF is a self sustaining closed loop sequence which is sometimes cyclic in nature but the nature of the sequence and its mechanism invariably changes over time. Furthermore, the mechanism by which any particular VF event is sustained will be related to the primary cause of the event. There are again various cardiac related abnormalities and trauma, which can promote a VF sequence in any human heart. These can be divided into two distinct groups, namely: Primary VF events and Secondary VF events.

Primary events are cases where the VF was an unexpected event. This can either be a sudden spontaneously initiated VF or a VF event due to some other sudden trauma or stress e.g. Acute Myocardial Infarction, Hypoxia, Lighting strike etc. Secondary events are those which occur although suddenly but predictably. These would include VF as a known risk of drug therapy and also patients who have a previous history of spontaneous VF events or rhythms which could promote VF. These two groups are managed differently by modern clinical response.

Secondary events are very well controlled by complex and miniaturised Implantable Cardiac Defibrillators (ICDs) which are surgically implanted within the chest and have electrodes directly connected to the heart. These devices continually monitor the hearts rhythm and deliver a shock to the heart if they detect the abnormal rhythm. Devices such as these have a very high

success rate for converting VF since they can respond very quickly.

Primary events however are not so easily controlled. Due to the fact that by nature they are entirely unpredictable, they invariably occur outside hospital and therefore occur in the absence of specialised equipment and or qualified personnel. When they do occur, the response time may be long because an average person will fail to recognise the seriousness of the condition. This means that the event can neither be quickly diagnosed nor effectively treated. The advent of the Portable Cardiac Defibrillator was a significant advance for emergency response teams allowing them access to a very specialised medical instrument outside hospital. The procedure means that primary events can now be treated almost as successfully as secondary events provided the emergency response team can be despatched and reach the patient in time. This delay could be further reduced if the use of Automatic External Defibrillators (AED's) becomes more widespread.

Unfortunately, there is a dilemma associated with external defibrillation. Unlike ICDs, external defibrillators apply the electrical shock across the thorax rather than directly across the heart, requiring much larger voltages in order to deliver the energy to the heart, necessary for termination of the VF rhythm. As a result of this high voltage, very high currents can occur within the thoracic cage and cause significant damage to heart tissue. Clearly this is

undesirable and defeats the purpose of the intended treatment. Furthermore, external defibrillation is probabilistic at best. For instance, having established an energy setting which has produced a successful defibrillation in one instance and then attempting to defibrillate with the same or higher energy setting may fail. Of even further interest is the fact that a significantly lower energy setting can be successful, all within the same individual.

For these reasons, low energy defibrillation has been a goal for investigators for many years. The object of the invention discussed here is not however that of low energy defibrillation but rather one of providing a means by which the probability of any defibrillation attempt being successful can be increased. It will become clear later however, that increasing the probability can mean that fewer lower amplitude shocks are actually required to terminate any given VF rhythm.

Attempts to reduce the energy delivered to patients requiring defibrillation have evolved from recommended dose protocols, for example a first shock of 200J and if this is unsuccessful then a second shock of 200J and then repeated shocks of 360J until successful or the attempts are to be abandoned; to energy dose based upon patient characteristics, for example changing initial discharge voltage, initial current or the discharge pulse width in order to deliver less energy to patients with a lower Trans-Thoracic Impedance (TTI).

Although these types of refinement have advantages they do not increase the probability of defibrillation

success and they can also have serious disadvantages. For example while decreasing the width of a shock pulse and keeping the initial discharge voltage constant for a low impedance patient means the subject receives a lower energy dose, the initial current flow through the subjects torso (and heart) is actually much greater and therefore very damaging.

Present theory projects that the state of the myocardium at the exact instant the shock is applied is actually the determining factor of a successful defibrillation attempt. Experiments changing the shape of the shock pulse itself have shown that different pulse shape characteristics can change the amount of energy required to terminate VF. It is widely accepted that although VF has a random appearance, it is characteristic and can in fact be successfully modelled.

Investigations in this field have shown that the success of a defibrillation attempt is governed by the ability of the applied shock pulse and its shape to successfully organise a critical mass of myocardial cells. Specifically, the critical mass of cells must be placed into the refractory (or recovery) state. If a critical mass can be organised in this way, the heart essentially pauses. The normal sinus pacemaker can then initiate the heart's normal activation sequence and normality is restored.

Recently however, investigators have shown that during VF the heart's organisational state changes over time, and specifically that there are instants during any VF

sequence at which the heart is in a more organisational state. Attempts by various investigators to identify these instants (called periods or instants of defibrillation susceptibility) have only been marginally successful. In 1988 Carlisle et al. synchronised the applied shock to the peaks, troughs and zero crossing points of the ECG during VF, without any significant success.

The object of the invention is therefore to provide a means for determining when a patient is susceptible to defibrillation whereby the probability of any defibrillation attempt being successful can be increased.

Accordingly, the invention provides an apparatus for determining when a patient is susceptible to defibrillation, the system comprising a plurality of electrodes for obtaining an electrocardiographic (ECG) signal from a patient, and data processing means for (a) determining a region of the ECG signal where such signal passes from a first threshold to a second threshold at least equal in magnitude to that of the first threshold and of opposite polarity thereto while the gradient of such signal remains within certain limits, (b) detecting the next following ECG signal peak, and (c) providing an output signal upon such detection.

The invention further provides defibrillation apparatus in which the occurrence of the output signal is used to trigger the application of a defibrillation voltage across the defibrillation electrodes.

In such case the electrodes providing the ECG signal may be the defibrillation electrodes themselves.

The first and second thresholds and gradient limits may be calculated automatically from measured parameters of the preceding ECG signal, or they may be empirically determined constant values.

In the embodiment to be described the data processing means is implemented in digital circuitry. However, it may alternatively be implemented in analog circuitry or a combination of analog and digital circuitry.

An embodiment of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Fig. 1 shows a single bipolar lead ECG showing a normal sinus beat measured from the body surface,

Fig. 2 is a diagram of a heart showing average cardiac vectors at four instants during a normal sinus beat corresponding to the ECG in Fig. 1,

Fig. 3 shows normal sinus rhythm,

Fig. 4 shows normal depolarisation and repolarisation of an isolated section of myocardium,

Fig. 5 is a typical bipolar ECG trace showing VF,

Fig. 6 shows a possible activation mechanism generating

a VF ECG trace,

Fig. 7 shows a single re-entrant activation loop,

Fig. 8 shows the VF epoch of Fig. 5 with time markers showing the defibrillation points identified by the prior art,

Fig. 9 illustrates the detection constraints imposed by the invention,

Fig. 10 shows the VF epoch of Fig. 5 with time markers showing the points identified by the invention,

Fig. 11 shows defibrillation apparatus embodying the invention,

Fig. 12 is a functional block diagram of the internal circuitry of the apparatus of Fig. 11,

Fig. 13 is a flow diagram of the operation of the shock point detector of Fig. 12,

Fig. 14 is an example of the use of the invention to terminate a VF sequence through delivery of a biphasic electrical shock, and

Fig. 15 is an example of the use of the invention terminating multiple re-entrant loops to form a dominant re-entrant loop.

The invention is based on the theory that the instants of susceptibility can be detected and quantified by the

average cardiac vector but that the amplitude and velocity of the approaching dominant wavefront is insufficient to accurately determine the instant of susceptibility. The instantaneous direction of the dominant wavefront and the nature of the myocardial organisation responsible for this direction is crucial to identifying the exact instant of susceptibility.

Fig. 1 shows an ECG obtained from a heart in normal sinus rhythm. Fig. 2 shows a diagrammatic sketch of the heart with the average cardiac depolarisation vectors superimposed. Each vector is called an average vector because it depicts the sum of all the myocardial cells activated at that particular point in time. The vectors are numerically labelled to portray the time sequence and can be related to the ECG trace Fig. 1 in order to appreciate the myocardial organisation at any given time instant. Note that the placement of the electrodes e1 and e2 shown in Fig. 2 (which in this case are the defibrillation electrodes ultimately used to shock the heart) determines the shape of the acquired ECG so the organisational state of the heart at any given time instant as determined by any given ECG lead is with reference to the direction resolved by that particular lead. Note also that normal Sinus rhythm is a very stable sequence repeated in a controlled manner by the heart, Fig. 3 shows an example ECG lead trace for reference.

Further considering Fig. 1, it can be appreciated that as the heart activates the average cardiac vector changes position from that denoted by t_1 to t_2 then to t_3 and finally to t_4. Of particular interest here is

that the ECG traces achieves maximum positive deflection between time instants t_2 and t_3. Referring now to Fig. 2 we see that between t_2 and t_3 the vector would be pointing in the direction of the axis between the two electrodes e_1 and e_2. It is a fundamental property of any bipolar ECG lead that when a depolarising myocardial wavefront is approaching along the axis of the lead, a maximum (positive) deflection will be measured and when it is retreating along the axis of the lead, a minimum (negative) deflection will be measured. Furthermore, if the wavefront is travelling in a direction perpendicular to the lead axis, no deflection (zero potential difference) will be measured. Before considering the properties of a VF sequence it must be appreciated that the ECG trace and the average cardiac vectors are a consequence of the activation wavefronts.

Fig. 4 shows how the activation of an isolated section of myocardium can be used to demonstrate a normal depolarisation and repolarisation sequence. Note that the average vectors are differentiated by a "- sign" for the depolarisation wave and a "+ sign" for the repolarisation wave. Above the tissue section we can also see the electrical trace which this isolated activation would produce measured from the two electrodes positioned either side of the section. The measured ECG trace shows the sharper, faster depolarisation wave inscribing a positive deflection as it approaches the positive electrode, this is then followed by the slower repolarisation wave which inscribes a negative deflection. The repolarisation wave is negative because it is of the opposite polarity

(positive rather than negative) as it approaches the positive electrode.

This particular activation sequence (with the repolarisation wave following behind the initial depolarisation wave) is typical of atrial tissue. Ventricular tissue actually repolarises in the opposite direction to which it initially depolarises. In terms of the measured ECG and Fig. 4 the only difference would be that for ventricular tissue, since the repolarisation wave would be receding away from the positive electrode it would actually inscribe a positive deflection in the ECG trace.

Now let us consider a VF trace and how myocardial tissue generates such a trace. Fig. 5 shows a typical epoch of VF. As we can see the trace does indeed appear random. This sequence is generated by tissue containing a varying number of wavefronts. Fig. 6 shows one possibility. Here we see that there are several wavefronts circulating without any apparent stimulus. These "loops" are self sustaining because the tissue is repolarising abnormally quickly so that the depolarising wavefront can actually reactivate the tissue rather than allowing the tissue to pause and wait for a normal stimulus. Note that since the individual wavefronts are completely independent, they will interfere so that the overall activation vector changes with time as presented by the ECG trace. Furthermore, in this particular example the "loops" are all the same diameter, this however would not necessarily be the case. It must now be appreciated

that at any given time instant the wavefronts can be seen to be adding together more than at other times, resulting in a higher amplitude activation vector being measured externally. At other times the wavefronts could interfere more destructively causing lower amplitude activation vectors to be measured.

Fig. 7 shows another possibility. Here only one large wavefront is shown circulating around the entire tissue section. The nature of this particular tissue activation pattern is the most fundamental type of self-sustaining "or re-entrant" activation. This more basic type of abnormal activation is more descriptive of a Ventricular Tachycardia sequence. Note that as this single wavefront rotates, at any time instant there are large areas of the tissue section which be can be noted as either depolarised or repolarised. In fact at any time instant there will be almost one half of the tissue section depolarised and one half repolarised. If we now deliver an electric shock at a random time instant to the tissue section, it is clear why such a shock may only sometimes be successful. At the instant the shock is applied, the areas of tissue that are depolarised will be unaffected, the areas that are repolarised (and therefore ready for activation) will begin to depolarise. Since these areas are depolarised earlier as a result of the shock stimulus, they cannot now be activated again by the already present circulating wavefront. The activation sequence is therefore terminated by interruption of the re-entrant loop. Note therefore that to successfully terminate such an abnormal sequence, the electrical

shock should be delivered at any time instant where the result of the shock would be to cause a significant amount of the tissue mass to be depolarised so as to interrupt the abnormal sequence. This implies that the electrical shock should be applied at any time instant where there is a significant amount of the tissue mass in a state of repolarisation.

If we now return to Fig. 6 and consider again how these individually circulating wavefronts interfere with each other over time, then we can see that the average cardiac vector and it's measurement (the ECG trace) is generated by the activation wavefronts combined. Note also that the act of measuring a threshold or a gradient at that threshold is not sufficient to determine the activation state of the tissue. Since the amplitude of the ECG trace is due to both the mass of tissue activation together with the direction in which it is activating they cannot be separated by a threshold. Furthermore the gradient only reveals the speed at which the overall wavefront is approaching or receding.

Fig. 8 shows time instant markers positioned at points along the trace of Fig. 5 where the prior art suggests susceptibility for defibrillation. It is the purpose of this invention to identify the optimum instant for susceptibility for interruption of a re-entrant loop by using the ECG trace to determine both from which direction the overall wavefront is coming and also in which direction it is going. This is achieved by noting a peak average cardiac vector of significant amplitude

and then detecting an amplitude of like magnitude but of opposite polarity immediately following the first noted peak. Furthermore the form of the ECG trace between these instants of opposite polarity must be appreciably linear (that is to say of relatively uniform gradient). The average cardiac vector presents this property when the overall activation is due to a significantly sized activation wavefront travelling away from a point far from the positive sensing electrode to a point near to the same electrode. Upon detection of a wavefront with this property at the positive electrode, there will be a significant mass of tissue having just been depolarised and therefore emerging from recovery ready for activation. Note also that this tissue mass will be have been travelling in a direction towards the positive electrode, meaning that the intracellular current flow within the tissue will also be directed in that direction. The defibrillating shock should therefore be delivered immediately upon detection of this instant so that the sequence can be successfully interrupted.

Furthermore it is crucial that the polarity of the defibrillation shock is such that the critical mass of cells are depolarised and that the shock is not applied across the tissue in a direction attempting to reverse repolarisation. A reverse polarity shock would require more energy since it would have to both reverse repolarisation and then depolarise the critical mass, a process which is very unlikely since having attempted to reverse repolarisation, the critical mass of cells will be less likely to depolarise properly and the VF

sequence would simply persist.

Thus, as shown in Fig. 9 for a negative-to-positive-going portion of the ECG signal, the object of the invention is to identify a region of the ECG signal where the signal passes from a negative threshold "-th" of significant magnitude to a positive threshold "+th" at least equal in magnitude to the negative threshold, while the gradient of the signal remains within certain limits. In Fig.9, provided the signal stays within the "channel" defined by the notional inclined parallel dotted lines separated by the horizontal distance $\delta\alpha$, it is assumed that the gradient has remained within the required limits. Having detected such a region of the ECG signal, the optimum point for defibrillation is at the next following ECG signal peak, i.e. local maximum, at which the defibrillation shock should be delivered.

The invention is equally applicable to positive-to-negative-going portions of the ECG signal, in which case one would detect a region of the ECG signal where the signal passes from a positive threshold of significant magnitude to a negative threshold at least equal in magnitude to the positive threshold, while the gradient of the signal remains within certain limits, and the optimum point for defibrillation would be at the next following local minimum of the ECG signal.

Fig. 10 shows the previous epoch of VF from Fig. 5 but here the above technique has identified only the instants tn1 and tn2 which were truly susceptible to defibrillation. As mentioned previously, the upper and lower thresholds, indicated in Fig. 10 by the

horizontal dashed lines, and the gradient limits may be calculated automatically from measured parameters of the preceding ECG signal, or they may be empirically determined constant values. In the case of Fig. 10 the thresholds are assumed to be a function of the average peak value of the preceding ECG signal.

An embodiment of the invention is shown in Figs. 11 to 13 and is based upon a known type of external defibrillation apparatus. Since the modifications necessary to embody the invention are internal, the apparatus has the outward appearance (Fig. 11) of a conventional external defibrillation apparatus.

Thus the apparatus includes a defibrillation unit 10 and a pair of defibrillation electrodes 12, 14 for application to a human torso 16, the electrodes being plugged into the unit 10. As well as being used to provide a defibrillation shock, the electrodes 12, 14 are also used as ECG electrodes to produce an ECG signal in known manner which is displayed on an ECG monitor 18 in the unit 10. A gain control knob 20 allows the amplitude of the signal trace to be adjusted on the monitor 18. The unit 16 also includes a rotary dial 22 to select the energy of the defibrillation shock to be applied to the patient, and a push button 24 which when pressed causes a capacitor inside the unit 16 to charge to a voltage determined by the setting of the selector 22. Finally, a further push button 26 is provided. In the conventional defibrillator an operator pushes this button to cause the capacitor to discharge through the electrodes 10, 12 to deliver a shock to the patient. However, in the

present case the internal circuitry of the unit 16 is modified so that pushing the button 26 merely enables a shock to be given, the actual timing of the shock being determined according to the principles discussed above with reference to Fig. 9.

Fig. 12 is a block diagram of internal circuitry of the unit 10. The individual blocks shown in Fig. 12 identify the main functions of the unit, and do not necessarily constitute separate and distinct parts of the circuitry.

Signal Conditioning and Amplification circuit 30 receives the signals from the individual defibrillation electrodes 12, 14 and generates therefrom in known manner the ECG signal for display on the monitor 18. Energy Select circuit 32 is responsive to the setting of the rotary dial 22 to establish the selected energy level and, when the push button 24 is pressed, Charge circuit 34 charges the capacitor to a level corresponding to the selected energy level.

In the prior art, and as indicated by the dashed line, Shock Enable circuit 36 is directly responsive to the operator pressing the push button 26 to provide an input to Shock Delivery circuit 38, causing the latter to immediately discharge the capacitor through the electrodes 12, 14 to deliver a defibrillation shock to the patient. However, in the present embodiment the Shock Enable circuit 36 provides instead an input to Trigger Shock circuit 40 interposed between circuits 36 and 38. The Trigger Shock circuit 40 also receives an input from Shock Point Detector circuit 42 which is

responsive to the ECG signal from circuit 30 to detect instants susceptible to defibrillation according to the principles of Fig. 9. The Shock Point Detector circuit 42 provides the said input to circuit 40 when such an instant is detected.

The Trigger Shock circuit 40 is essentially an AND circuit and, when it receives an input simultaneously from both circuits 36 and 42, it provides an input to the Shock Delivery Circuit 38 which causes the latter to immediately discharge the capacitor through the electrodes 12, 14 to deliver a defibrillation shock to the patient. Thus, as compared to the conventional external defibrillator which provides a defibrillation shock immediately the button 26 is pressed, which can occur at any arbitrary point during the ECG cycle due to the rapid changes in the signal and the relatively slow reaction of the human operator, in the present apparatus when the button 26 is pressed the apparatus waits until the Shock Point Detector circuit 42 identifies an instant susceptible to defibrillation and only then administers the shock. Such instant will typically occur a fraction of a second after the button 26 is pressed, and thus the button 26 must be held down until the shock is given. Optionally, if no suitable instant is detected within a predetermined time, say about two seconds, after the button 26 is pressed, the apparatus may be designed to administer a shock at that point anyway. The shock is preferably an n-phasic truncated exponential shock where n is greater than one. That is to say, it consists of several truncated exponential voltage pulses of alternating polarity. In particular it may be a biphasic truncated exponential

shock.

The implementation of circuits 30 to 38 is well known in the art and does not need further description. Also, circuit 40 is essentially an AND circuit and is readily implemented by those skilled in the art. The function of the Shock Point Detector circuit 42 is performed in this embodiment by a suitably programmed microprocessor. In order to allow the microprocessor to process the ECG signal an analog-to-digital (A/D) converter (not shown) is used to convert the analog ECG signal to digital form.

Fig. 13 is a flow diagram of the program which is run on the microprocessor to identify the instants susceptible to defibrillation. The program starts when the push button 26 is pressed. Step 50 repeatedly tests the ECG signal to detect the ECG signal crossing a predetermined negative threshold in a positive-going direction, and when such a crossing is detected step 52 analyses the signal to determine its instantaneous gradient. Step 54 tests the gradient thus determined for being within predetermined limits. If the gradient is not within the limits, control passes back to step 50. If it is within limits, step 56 tests to determine if the signal has crossed a predetermined positive threshold at least equal in magnitude to that of the negative threshold. If it has, step 58 detects the next following peak (local maximum) and step 60 provides an output to the Trigger Shock circuit 40. If, however, step 56 determines that the signal has not crossed the positive threshold, control returns to step 52 and steps 52 to 56 are run through again. Thus, as

time progresses from the crossing detection at step 50 the program repeatedly tests the gradient for being within limits, until either the signal crosses the positive threshold, in which case the next following peak is detected, or the gradient falls outside the limits, in which case control reverts to step 50 to look for the next crossing of the negative threshold.

Fig. 14 shows the invention having identified the correct instant of susceptibility and a biphasic truncated exponential shock was delivered to successfully terminate the VF event. The invention can also be used to terminate VF sequences sustained by multiple re-entrant loops as described above and shown in Fig. 6. In this instance the invention identifies the instant of greatest susceptibility and a first shock is delivered. Fig. 15 shows this process. As the figure shows, the purpose of the first shock is not to activate a critical mass and thereby terminate the VF sequence, but rather to just merge some of the small loops into one bigger loop. Successive shocks can therefore merge the loops into bigger and bigger loops until a final shock terminates the VF sequence.

The invention has been used to identify the instant of susceptibility in each case. This means that the energy required to defibrillate (either single shock or through multiple sequential shocks) is considerably less than would be required to activate a critical mass at a time instant that is not susceptible.

Although the above embodiment has used the same electrodes for both defibrillation and to provide the

ECG signal which is analysed to determine the instant of susceptibility to defibrillation, the ECG signal could alternatively be derived from separate electrodes.

Also, although the foregoing has described the invention in the context of an external defibrillator, i.e. where the electrodes are connected externally to the patient's body, it will be clear to those skilled in the art that the invention may be used to determine the instant of susceptibility to defibrillation in the case of implanted electrodes which are connected directly to the heart's surface.

The invention is not limited to the embodiments described herein which may be modified or varied without departing from the scope of the invention.

CLAIMS

1. An apparatus for determining when a patient is susceptible to defibrillation, the system comprising a plurality of electrodes for obtaining an electrocardiographic (ECG) signal from a patient, and data processing means for (a) determining a region of the ECG signal where such signal passes from a first threshold to a second threshold at least equal in magnitude to that of the first threshold and of opposite polarity thereto while the gradient of such signal remains within certain limits, (b) detecting the next following ECG signal peak, and (c) providing an output signal upon such detection.

2. An apparatus as claimed in claim 1, wherein the first threshold is a negative threshold and the second threshold is a positive threshold.

3. An apparatus as claimed in claim 1, wherein the first threshold is a positive threshold and the second threshold is a negative threshold.

4. A defibrillator including an apparatus as claimed in claim 1, 2 or 3 wherein the occurrence of the output signal is used to trigger the application of a defibrillation voltage across defibrillation electrodes.

5. A defibrillator as claimed in claim 4, wherein the electrodes providing the ECG signal are also the defibrillation electrodes.

6. A defibrillator as claimed in claim 4 or 5, wherein the defibrillation voltage is an n-phasic truncated exponential voltage where n is greater than one.

7. A defibrillator as claimed in claim 4, 5 or 6, wherein the defibrillation voltage is a biphasic truncated exponential voltage.

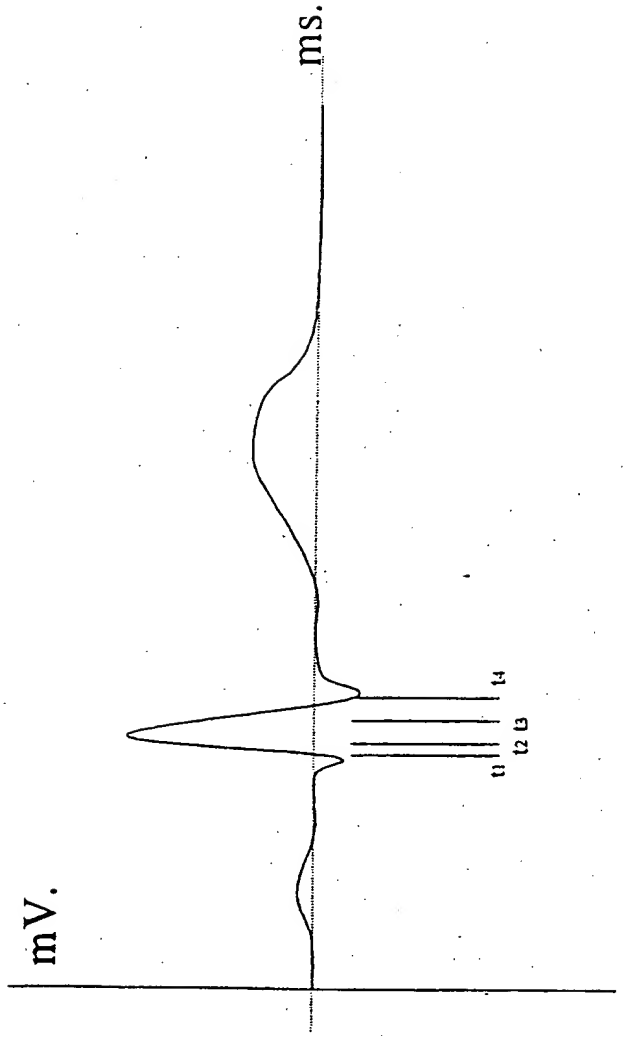
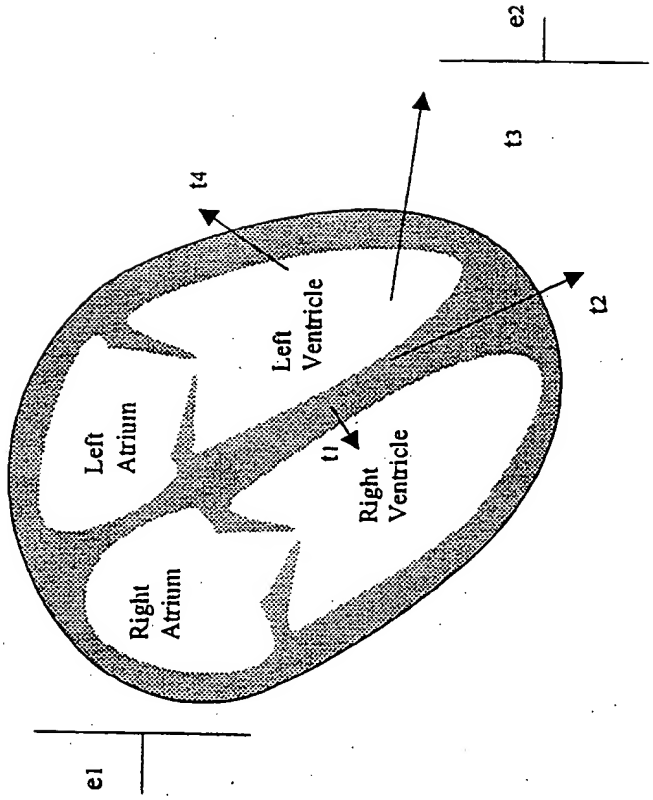


Fig.1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t3
t4
t2
Left Ventricle
Left Atrium
t1
Right Ventricle
Right Atrium
e1

Fig.2

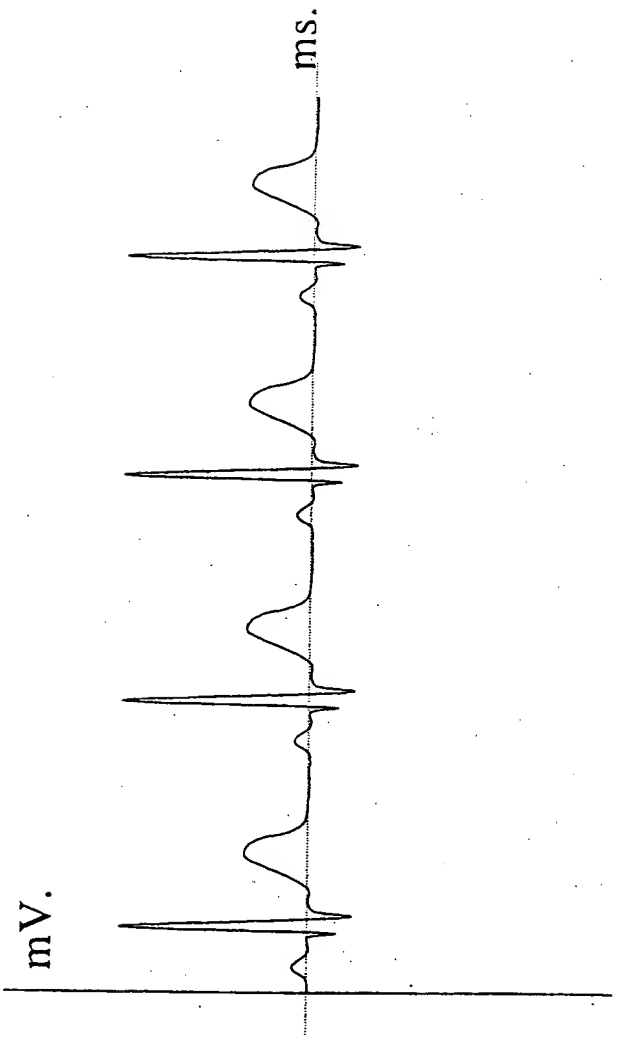


Fig.3

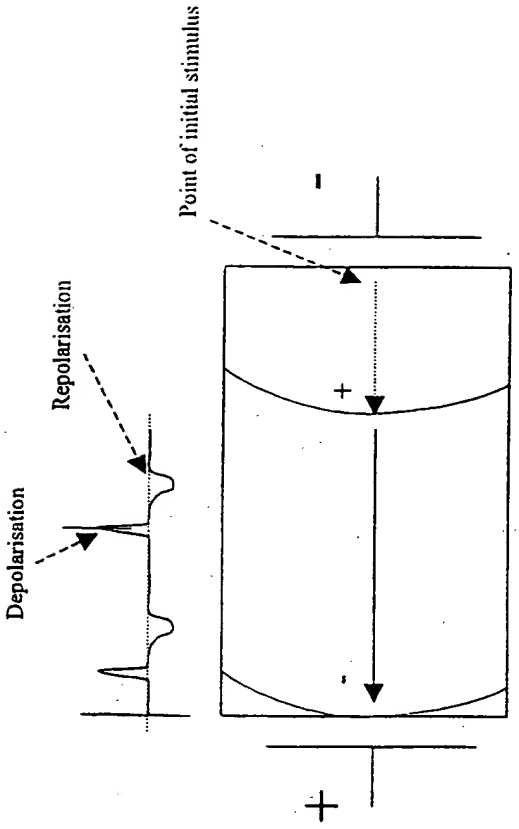

Point of initial stimulus
Repolarisation
Depolarisation
-
+
+
-

Fig.4

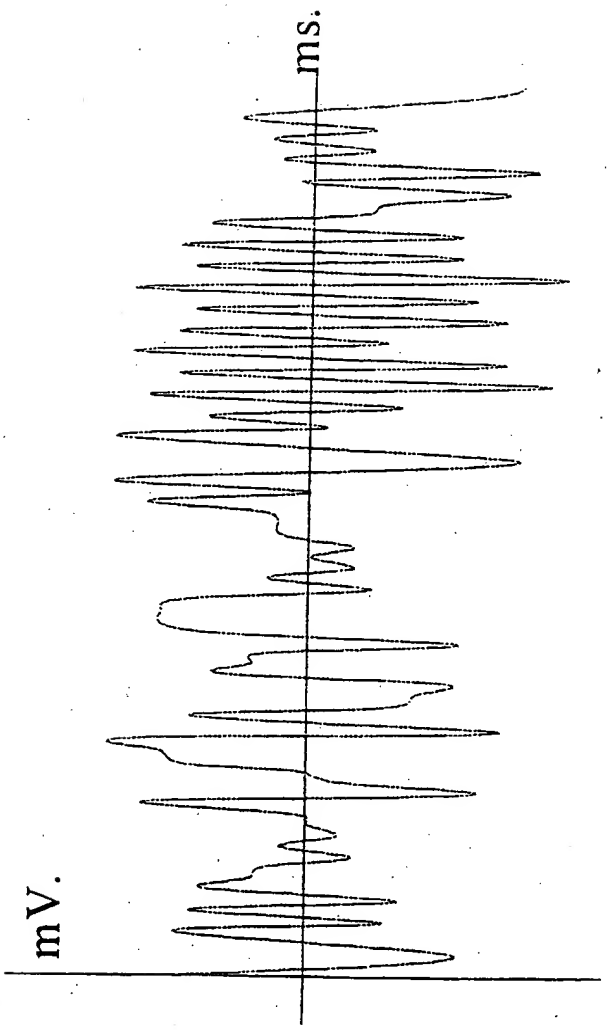


Fig.5

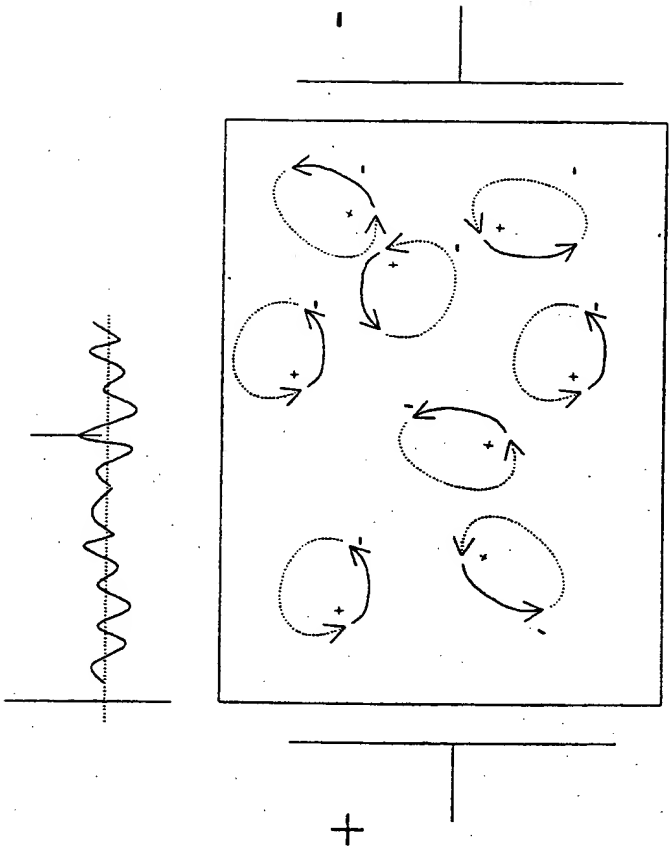


Fig.6

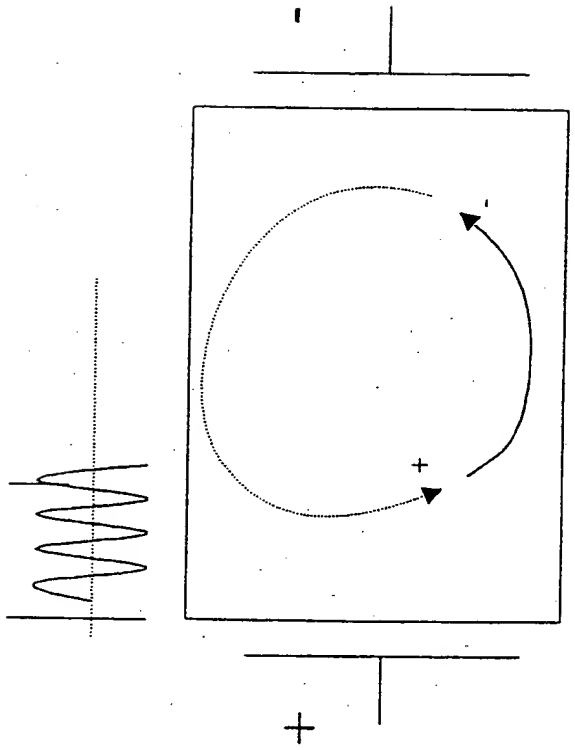


Fig.7

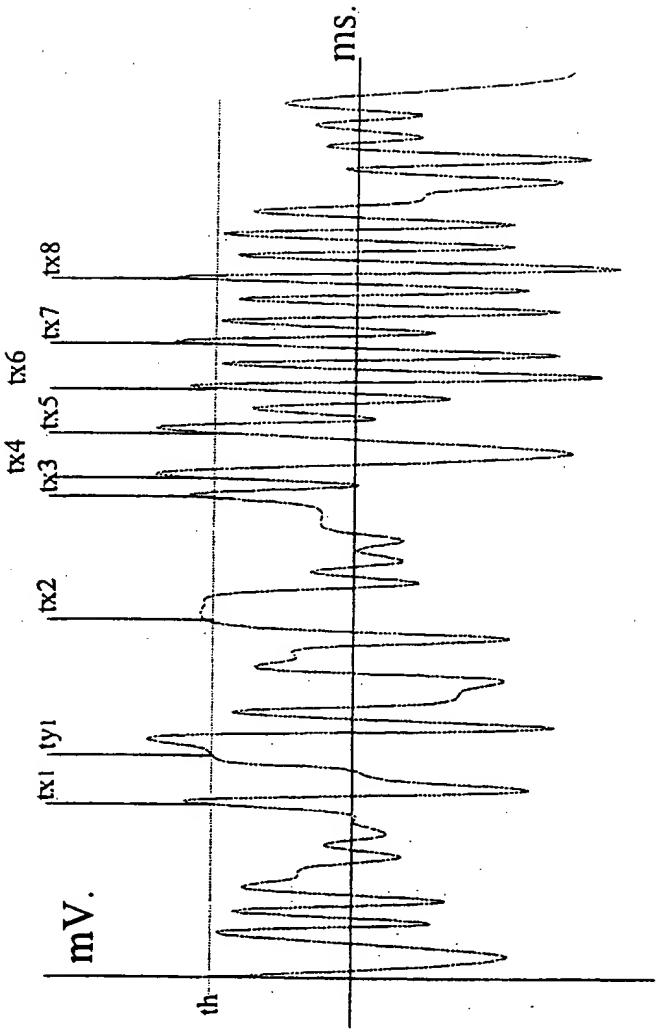


Fig.8

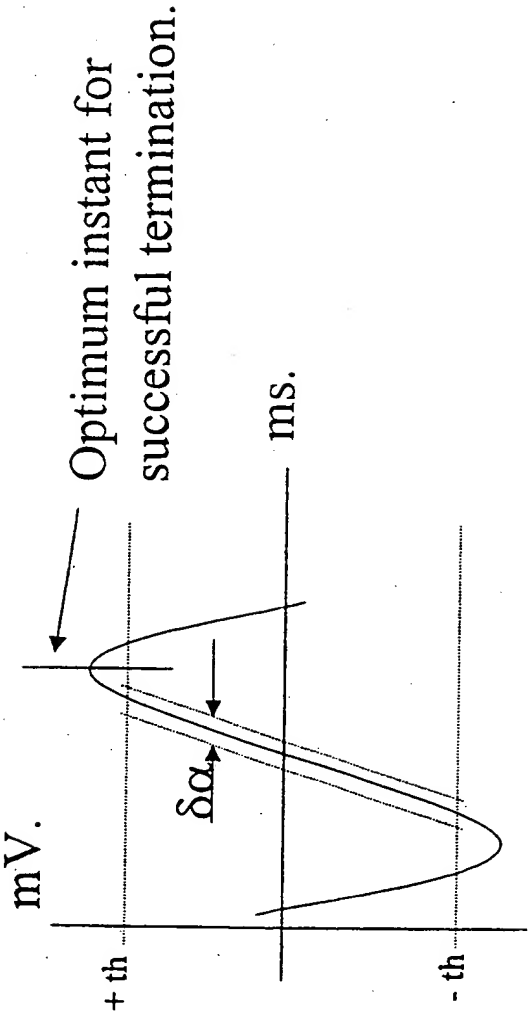


Fig.9

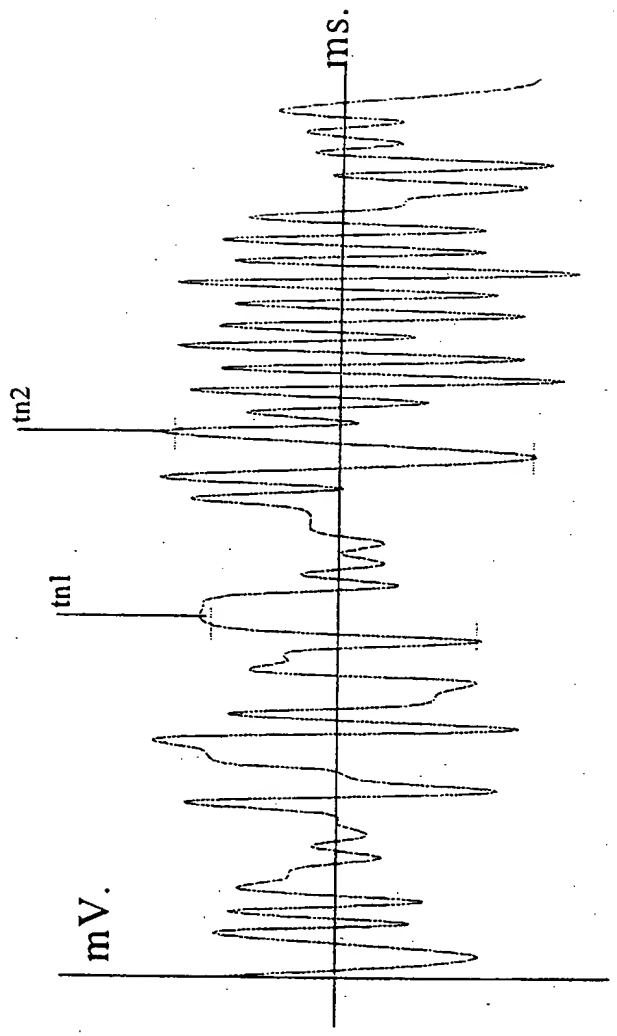


Fig.10

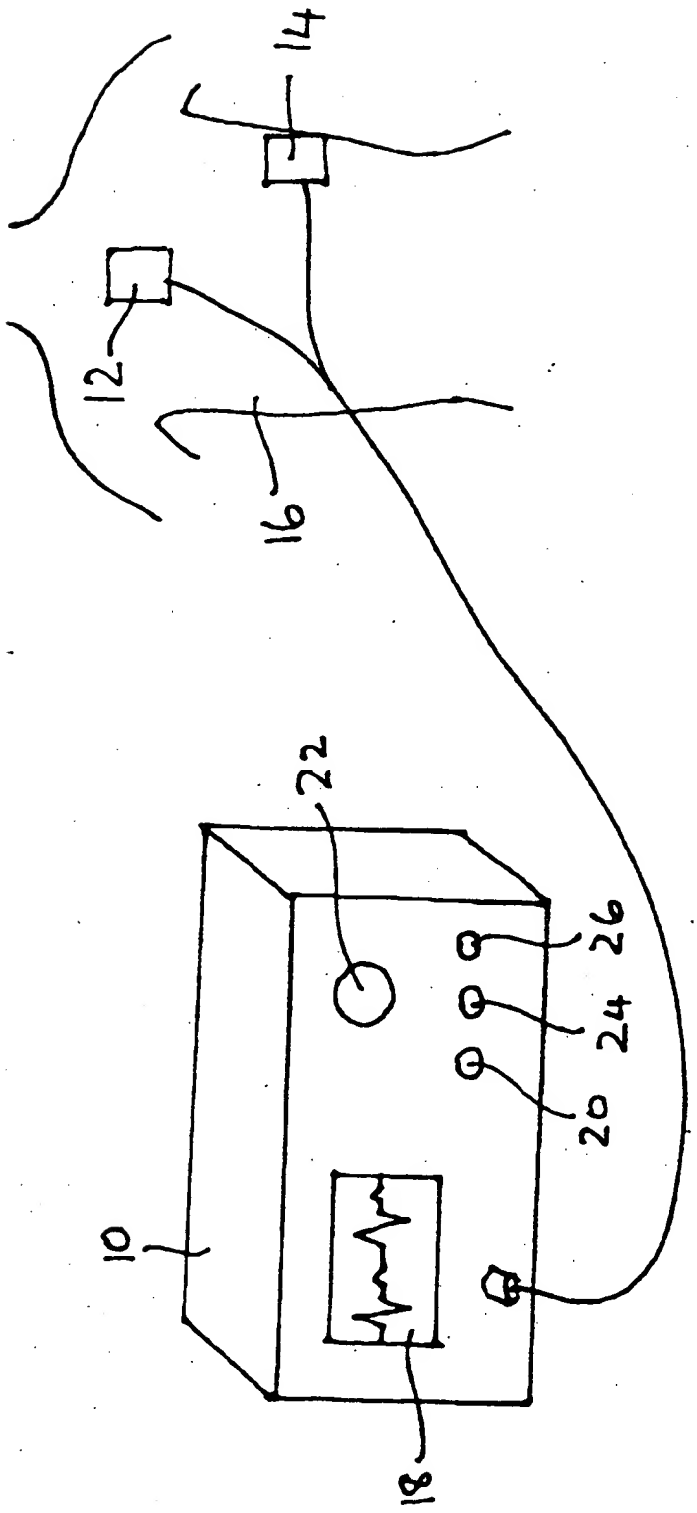
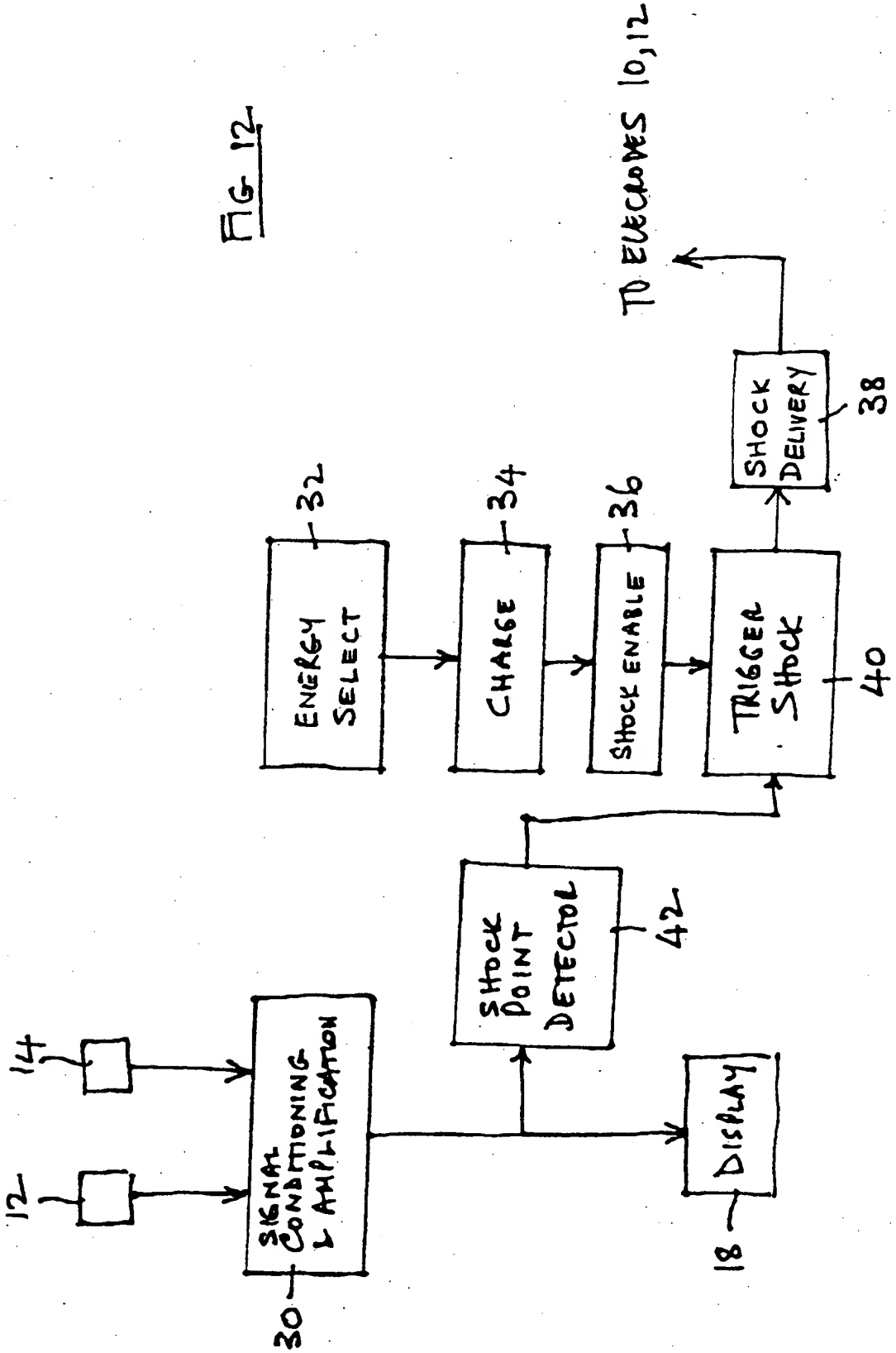


FIG. 11

FIG 12


TO ELECTRODES 10,12
SHOCK DELIVERY
38
ENERGY SELECT
32
CHARGE
34
SHOCK ENABLE
36
TRIGGER SHOCK
40
SHOCK POINT DETECTOR
42
SIGNAL CONDITIONING & AMPLIFICATION
30
DISPLAY
18
14
12

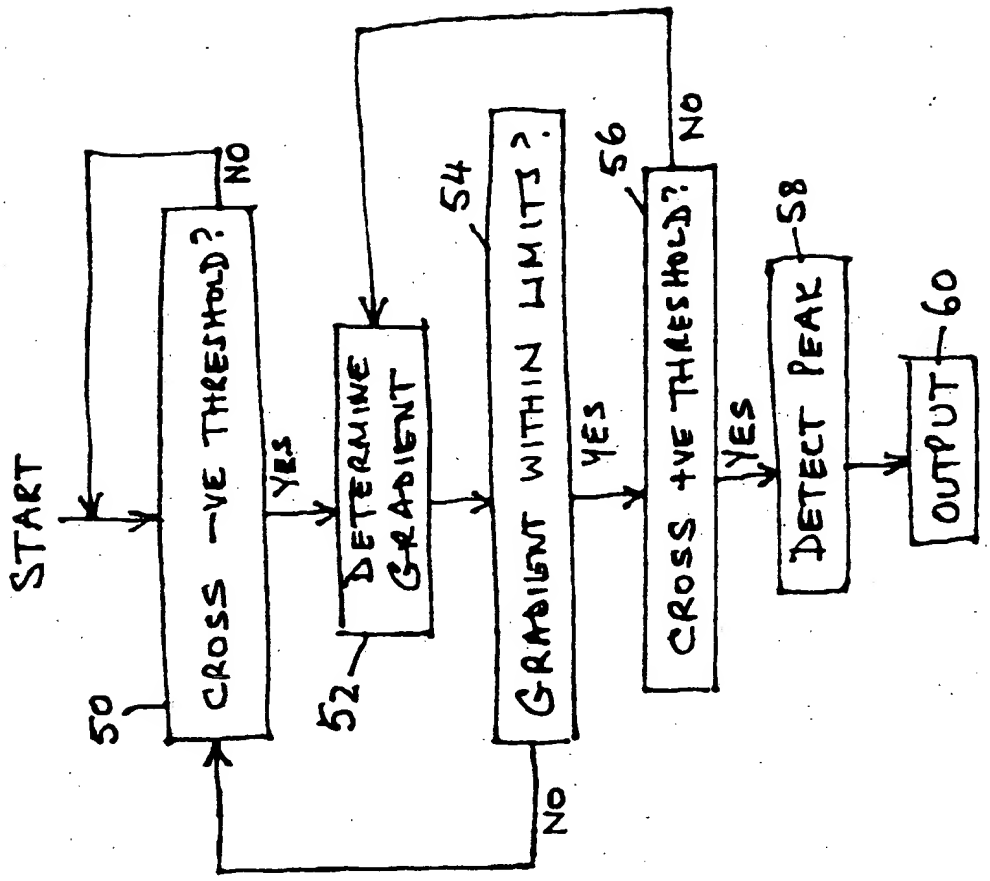

START
CROSS -VE THRESHOLD?
NO
YES
50
DETERMINE GRADIENT
52
GRADIENT WITHIN LIMITS?
54
NO
YES
CROSS +VE THRESHOLD?
56
NO
YES
DETECT PEAK
58
OUTPUT
60

FIG. 13

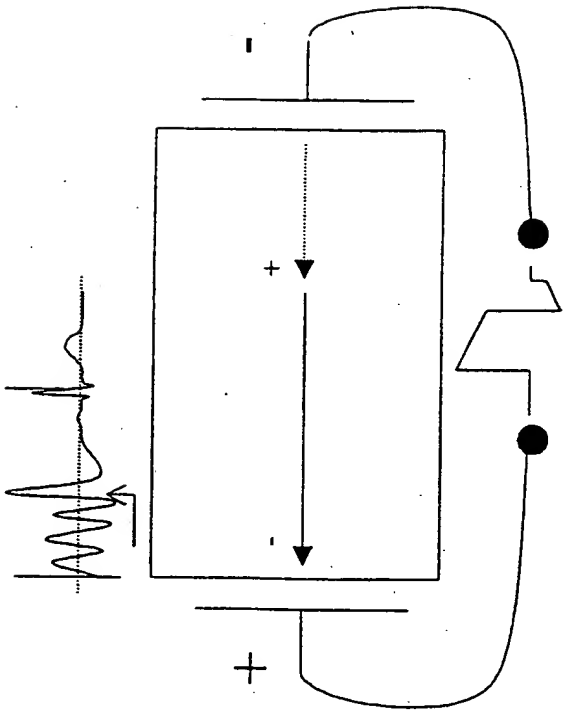


Fig.14

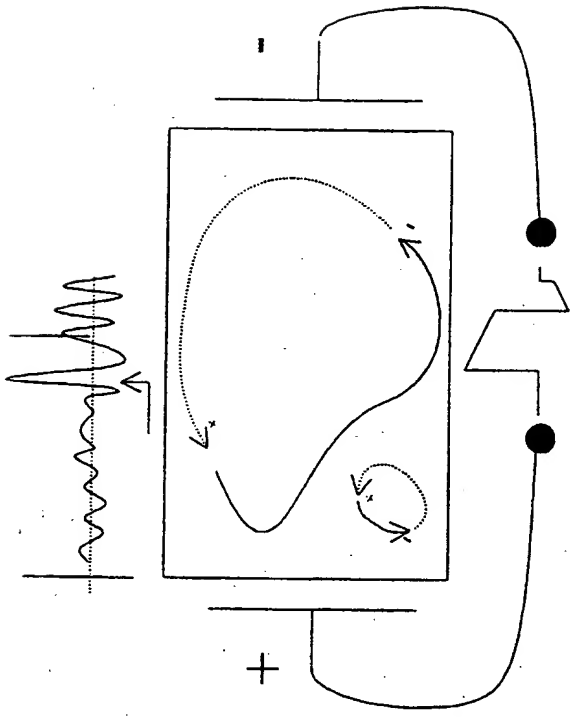


Fig.15

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 00/00205

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/39 A61B5/0456

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N A61B G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 545 182 A (STOTTS LAWRENCE J ET AL) 13 August 1996 (1996-08-13) column 4, line 61 -column 5, line 29 column 9, line 15-32	1
A	EP 0 674 917 A (VENTRITEX INC) 4 October 1995 (1995-10-04) column 6, line 23-55	1
A	US 5 578 062 A (ALT ECKHARD ET AL) 26 November 1996 (1996-11-26) column 5, line 29-43 column 7, line 17-35 column 8, line 22-30	1
A	US 5 507 778 A (FREEMAN GARY A) 16 April 1996 (1996-04-16) column 5, line 13-27	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

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Date of the actual completion of the international search	Date of mailing of the international search report
29 May 2000	07/06/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Grossmann, C.

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ERNATIONAL SEARCH REPOR.

...formation on patent family members

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PCT/IB 00/00205

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